

Remarks

The Board of Appeals in its Decision on Appeal entered a new ground of rejection under 35 U.S.C. §112. Accordingly, in response thereto, the foregoing Amendment is presented to respond to the new ground of rejection and reopen prosecution. Claim 1 is amended to better define the invention by cancelling the language “non-liposomal” and “non-polar”, and to indicate the carrier is a phosphatidylcholine and polyglycol multilamellar liquid crystal carrier. The carrier as defined in the claims is not a liposome. The application at Page 5, ¶ [0013] specifies that:

“The PC composition, in liquid crystal phase, is loosely arranged in multilamellar fashion, with the drug being bonded and entrapped within the lipid bilayers formed by the PC composition. This forms a loosely arranged, yet stable, PC composition carrier-drug complex.”

The present invention is a method of formulating a stable topical transdermal compositions. The importance of the present invention is that it provides a method of formulating stable topical transdermal compositions that are stable room temperature. [Specification, ¶21]. This is a significant benefit to patients located in geographic regions such as Africa or Asia where reliable refrigeration may not be available. A unique element of the claimed invention is that the method of formulating uses a phosphatidylcholine and polyglycol multilamellar liquid crystal carrier. The phosphatidylcholine and polyglycol multilamellar liquid crystal carrier has bilayers entrapping the compound to be administered. The structure of the phosphatidylcholine and polyglycol multilamellar liquid crystal carrier is obtained through the claimed method as specifically described in the Specification, at ¶[0019](Page 7, lines 10-23); and ¶[0018](Page 7, lines 4-9).

It is submitted that the prior rejections of record are not applicable. The rejections under 35 USC §103 over Amselen et al (US 5662932) or Lynch (US 2002/0153509) in view of Hansen (US 4614730) and Patel (US6294192), and with respect to claims 2-6, 8, 15 and 16, Chaiyawat (U.S. 6538061) and Brieva (U.S. 5985298) are not reasonable

as none of them disclose or suggest a ***multilamellar liquid crystal*** carrier, as opposed to a liposome or other crystal structure.

It is submitted that the presently claimed invention is patentable over the previously cited references and issuance of a Notice of Allowance is respectfully requested.

Respectfully submitted,

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